

FORM PTO 1390
(REV 11-2000)

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTORNEY'S DOCKET NUMBER

TRANSMITTAL LETTER TO THE UNITED STATES
DESIGNATED/ELECTED OFFICE (DO/EO/US)
CONCERNING A FILING UNDER 35 U.S.C. 371

CERA-236

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)

10/019793

INTERNATIONAL APPLICATION NO.

PCT/EP00/05992

INTERNATIONAL FILING DATES

28 June 2000

PRIORITY DATE CLAIMED

15 July 1999

TITLE OF INVENTION

CERAMIC SANDWICH INSERT FOR AN ARTIFICIAL HIP JOINT

APPLICANT(S) FOR DO/EO/US

Uwe BUNZ, Ernst HOCH, Hans-Georg PFAFF and Robert RACK

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing 35 U.S.C. 371
3. ☒ This is an express request to begin national examination procedures (35 U.S.C. 371 (f)). The submission must include items (5), (6), (9) and (21) indicated below.
4. ☐ The US has been elected by the expiration of 19 months from the priority date (PCT Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371 (c)(2))
 - a. ☒ is attached hereto (required only if not communicated by the International Bureau).
 - b. ☒ has been communicated by the International Bureau.
 - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☒ An English language translation of the International Application as filed (35 U.S.C. 371 (c)(2)).
 - a. ☒ is attached hereto.
 - b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
 - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
 - b. ☐ have been communicated by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☐ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)).
9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).
10. ☐ An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).

Items 11 to 20 below concern document(s) or information included:

11. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☒ A **FIRST** preliminary amendment.
14. ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
15. ☐ A substitute specification.
16. ☐ A change of power of attorney and/or address letter.
17. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 - 1.825.
18. ☐ A second copy of the published international application under 35 U.S.C. 154(d)(4).
19. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
20. ☒ Other items or information: PCT/IPEA/416; PCT/RO/105; PCT/IPEA/401

U.S. APPLICATION NO (if known, see 37 CFR 1.5) 10/019793		INTERNATIONAL APPLICATION NO PCT/EP00/05992		ATTORNEY'S DOCKET NUMBER CERA-236	
17. <input checked="" type="checkbox"/> The following fees are submitted:				CALCULATIONS PTO USE ONLY	
BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)): <input type="checkbox"/> Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO \$1040.00 <input type="checkbox"/> International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO \$890.00 <input checked="" type="checkbox"/> International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO \$740.00 <input type="checkbox"/> International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4) \$710.00 <input type="checkbox"/> International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4) \$100.00					
ENTER APPROPRIATE BASIC FEE AMOUNT = Surcharge of \$ <u>130.00</u> for furnishing the oath or declaration later than <input type="checkbox"/> 20 <input checked="" type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(e)).				\$ 890.00	
				\$ 130.00	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	12	11- = 0	X 18.00	\$	
Independent claims		1-3 = 1	X	\$	
MULTIPLE DEPENDENT CLAIM(s) (if applicable)				X \$	
TOTAL OF ABOVE CALCULATIONS =				\$ 1020.00	
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.				\$	
SUBTOTAL =				\$ 1020.00	
Processing fee of \$ _____ For furnishing the English translation later than <input type="checkbox"/> 20 <input checked="" type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(f)). +				\$	
TOTAL NATIONAL FEE =				\$ 1,020.00	
Fee for recording the enclosed assignment (37 CFR 1.21 (h)). Assignment Must be accompanied by appropriate cover sheet (37 CFR 3.28, 3.31) (_____ per property). +				\$ 00	
TOTAL FEES ENCLOSED =				\$ 1,020.00	
				Amount to be Refunded: \$	
				Charged: \$	
a. <input checked="" type="checkbox"/> A check in the amount of \$ <u>\$1,020.00</u> to cover the above fees is enclosed. b. <input checked="" type="checkbox"/> Please charge my Deposit Account No. <u>50-0624</u> in the amount of \$ _____ to cover the above fees. A duplicate copy of this sheet is enclosed. c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required or credit any overpayment to my Deposit Account No. <u>50-0624</u> . A duplicate copy of this sheet is enclosed.					
NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137 (a) or (b)) must be filed and granted to restore the application to pending status.					
SEND ALL CORRESPONDENCE TO James R. Crawford FULBRIGHT & JAWORSKI L.L.P. 666 Fifth Avenue New York, New York 10103 (212) 318-3148 Customer No. 24972			SIGNATURE _____ NAME _____ James R. Crawford _____ 39,155		

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CERA-236

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) : Uwe Bunz, et al.
Serial No. : Please assign
Filing Date : Herewith
For : CERAMIC SANDWICH INSERT FOR AN ARTIFICIAL HIP
JOINT

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

January 4, 2002

PRELIMINARY AMENDMENT

Sir:

Prior to examination please amend the application as follows:

IN THE CLAIMS

Cancel claims 1-12, without prejudice and add the following claims:

13. Sandwich insert having an inner ceramic sliding cup which is surrounded by a plastics cover for insertion into an outer metal shell of an artificial hip joint, characterized in that the sliding cup has a stud at its outer end that is remote from the opening.
14. Sandwich insert according to claim 13, wherein the stud is arranged on the central axis of the sliding cup.
15. Sandwich insert according to claim 13, wherein the stud has an axial length of 1 – 8 mm, preferably approximately 2 mm.
16. Sandwich insert according to claim 13, wherein the stud is arranged in the plastics cover by means of a fit.
17. Sandwich insert according to claim 13, wherein the stud projects into the plastics cover or projects completely through it.

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18. Sandwich insert according to claim 13, wherein the stud is surrounded at least in part by the plastics cover.

19. Sandwich insert according to claim 13, wherein the cross section of the stud forms an n-sided body, preferably with $n = 2, 4, 5$ or 6 .

20. Sandwich insert according to claim 13, wherein the cross section of the stud forms a polygon.

21. Sandwich insert according to claim 13, wherein the cross section of the stud is oval.

22. Sandwich insert according to claim 13, wherein the sliding cup is of a spherical or a stepped structural form on its outside.

23. Sandwich insert according to claim 13, wherein the plastics cover embraces the sliding cup at its open end.

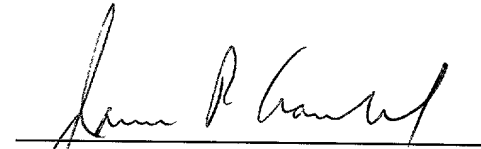
24. Sandwich insert according to claim 13, wherein the sliding cup is pressed into the plastics cover.

REMARKS

Applicants respectfully request entry of the foregoing amendment. Early and favorable action on the pending Claims is earnestly solicited. If any fees are due to maintain pendency of this application, authorization is granted to charge such fees to Deposit Account No. 50-0624.

Respectfully submitted,

FULBRIGHT & JAWORSKI, L.L.P.

A handwritten signature in dark ink, appearing to read "James R. Crawford", is written over a horizontal line.

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10/019793
JC13 Rec'd PCT/PTO 04 JAN 2002

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Ceramic sandwich insert for an artificial hip joint

5 The invention relates to a sandwich insert having an inner ceramic sliding cup, which is surrounded by a plastics cover, for insertion into an outer metal shell of an artificial hip joint.

10 An artificial hip joint as a rule consists of a sliding cup which is inserted into an outer metal shell either directly or by way of a plastics cover. This metal shell is implanted in the pelvic bone. The combination of sliding cup and plastics cover is termed a sandwich insert.

15 A shaft, on which there is arranged a ball head that articulates in the sliding shell, is implanted in the femur.

20 In the case of artificial hip joints it is possible that the ball-head shaft will strike against the acetabulum time and time again. If the impact forces are sufficiently great, this can result in the mechanical acetabulum-composite breaking up. In particular, sandwich socket systems are at risk here, since the polyethylene (PE) that is predominantly used can only put up insufficient resistance against these forces of impact.

25 Sandwich inserts are produced in various ways.

30 In one system, the ceramic sliding cup or the insert respectively has plastics material injection-moulded around it, with recesses being arranged on the sliding shell. What is disadvantageous about this is the fact that the polyethylene (PE)-properties that result when the same is heated are inferior. Furthermore, there is

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5 a thermal shock for the ceramic sliding cup. In addition to the outlay on injection-moulding on account of the injecting mould and the handling of the hot portions, the large amount of construction space that is required is disadvantageous.

10 In the case of an alternative system, the sliding shell is anchored by a conical clamp in the plastics cover, with there being to some extent, instances of low resistance of the composite component. The disadvantage here as well is the large amount of construction space that is required.

15 The process of pressing the sliding cup into the plastics cover in the warm state is also preferably employed. In this connection, however, there occur to some extent instances of composite component strength that are too low. Moreover, narrow tolerances must be observed on account of the press-connection.

20 The underlying object of the invention is to improve a sandwich insert in accordance with the preamble of claim 1 in such a way that a high level of resistance to sudden change is achieved with a small amount of construction space being required.

30 In accordance with the invention this object is achieved by the sliding cup having a stud at its outer end that is remote from the opening, whereby the resistance to sudden change is substantially increased, with a small amount of construction space being required, since the stud necessitates almost no increase in construction space.

35 Advantageously, the stud is arranged on the central axis or the axis of rotation of the sliding cup and has

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an axial length of 1 - 8 mm, preferably approximately 2 mm. This length suffices in order to increase the resistance to sudden change. However, other lengths can also be used.

5

In a preferred embodiment, the stud is arranged in the plastics cover by means of a fit. This can be an interference fit, a transition fit or a close clearance fit, depending on the desired resistance-configuration.

10

The stud can project completely through the plastics cover, project into it or else be surrounded at least in part by the plastics cover. It is preferably even completely surrounded by the plastics cover.

15

The cross section of the stud forms an n-sided body with $n = 2, 4, 5$ or 6 . Alternatively, the cross section of the stud can even form a polygon or be oval.

20

The sliding shell is preferably of a spherical or a stepped structural form on its outside. Spherical structural forms require a very small amount of construction space.

25

In an advantageous embodiment, the plastics cover embraces the sliding shell at its open end.

The sandwich insert is preferably produced by pressing the sliding shell into the plastics cover.

30

Further features of the invention follow from the figures which are described in the following and in which

35

Figure 1 shows a sandwich insert in accordance with the invention in a spherical structural form;

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Figure 2 shows a sandwich insert in accordance with the invention in a stepped structural form; and

5 Figure 3 shows advantageous configurations of the cross sections of the stud.

10 Figure 1 shows a sandwich insert having a sliding cup 1 of spherical structural form. During production, this sliding shell 1 is pressed into the plastics cover 2. The plastics cover 2 preferably consists of polyethylene (PE). The upper edge of the sliding shell is constructed so as to be flush with the upper edge of the plastics cover 2. In order to increase the
15 resistance to sudden change, that is, also to anchor the sliding cup 1 in the plastics cover 2 in a better way, a stud 3 is arranged at the end of the sliding shell that is remote from the opening on the axis of rotation or central axis 4. This stud 3 projects into the plastics cover 2 in this embodiment.
20

25 Figure 2 shows an alternative embodiment with a stepped structural form for the sliding cup 1 on the outside thereof. Here, as well, a stud 3 is arranged on the central axis 4 and is completely surrounded here by the plastics cover 2. The axial length of the stud 3 is then approximately 2 mm.

30 In view of the fact that the sliding shell 1 is pressed into the plastics cover 2 during production, the stud 3 is inserted in the plastics cover 2 by means of a fit.

35 At its open end the plastics cover 2 embraces the sliding cup 1, thereby improving the securement. The collar 5 of the plastics cover 2 that rests on the upper side of the sliding cup 1 covers almost half of

the upper edge.

Figure 3, by way of cross sections, shows the various configurations of the stud 3. In each case a cross section of the stud 3 is shown at right angles to the central axis 4.

Figure 3a shows an oval cross section for the purpose of increasing the resistance to rotation; Figure 3b shows a two sided body; and Figure 3c shows a polygonal cross section. The latter has the advantage of being able to be produced by turning with a comparatively high level of removal of plastics material.

Figure 3d shows a four sided or a square stud 3; and Figure 3e shows a five sided body as a stud 3. Advantageously, also possible is a six sided body for the stud.

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Claims

1. Sandwich insert having an inner ceramic sliding cup (1), which is surrounded by a plastics cover (2), for insertion into an outer metal shell of an artificial hip joint, characterized in that the sliding cup (1) has a stud (3) at its outer end that is remote from the opening.

2. Sandwich insert according to claim 1, characterized in that the stud (3) is arranged on the central axis (4) of the sliding cup (1).

3. Sandwich insert according to claim 1 or 2, characterized in that the stud (3) has an axial length of 1 - 8 mm, preferably approximately 2 mm.

4. Sandwich insert according to one of claims 1 to 3, characterized in that the stud (3) is arranged in the plastics cover (2) by means of a fit.

5. Sandwich insert according to one of claims 1 to 4, characterized in that the stud (3) projects into the plastics cover (2) or projects completely through it.

6. Sandwich insert according to one of claims 1 to 4, characterized in that the stud (3) is surrounded at least in part by the plastics cover (2).

7. Sandwich insert according to one of claims 1 to 6, characterized in that the cross section of the stud (3) forms an n-sided body, preferably with $n = 2, 4, 5$ or 6.

8. Sandwich insert according to one of claims 1 to 6,

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characterized in that the cross section of the stud (3) forms a polygon.

5 9. Sandwich insert according to one of claims 1 to 6, characterized in that the cross section of the stud (3) is oval.

10 10. Sandwich insert according to one of claims 1 to 9, characterized in that the sliding cup (1) is of a spherical or a stepped structural form on its outside.

15 11. Sandwich insert according to one of claims 1 to 10, characterized in that the plastics cover (2) embraces the sliding cup (1) at its open end.

12. Sandwich insert according to one of claims 1 to 11, characterized in that the sliding cup (1) is pressed into the plastics cover (2).

2001 DEC 20 14:06 HASELTINE LAKE LONDON

(12) NACH DEM VERTRAG ÜBER DIE INTERNATIONALE ZUSAMMENARBEIT AUF DEM GEBIET DES
PATENTWESENS (PCT) VERÖFFENTLICHTE INTERNATIONALE ANMELDUNG

(19) Weltorganisation für geistiges Eigentum
Internationales Büro



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(51) Internationale Patentklassifikation⁷: **A61F 2/34**

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(21) Internationales Aktenzeichen: PCT/EP00/05992

(22) Internationales Anmeldedatum:
28. Juni 2000 (28.06.2000)

(74) Anwälte: **SCHERZBERG, Andreas** usw.; Dynamit Nobel Aktiengesellschaft, Patentabteilung, D-53839 Troisdorf (DE).

(25) Einreichungssprache: Deutsch

(81) Bestimmungsstaaten (*national*): CA, CZ, JP, US.

(26) Veröffentlichungssprache: Deutsch

(84) Bestimmungsstaaten (*regional*): europäisches Patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

(30) Angaben zur Priorität:
199 33 206.1 15. Juli 1999 (15.07.1999) DE
100 00 521.7 8. Januar 2000 (08.01.2000) DE

(71) Anmelder (für alle Bestimmungsstaaten mit Ausnahme von US): **CERAMTEC AG INNOVATIVE CERAMIC ENGINEERING** [DE/DE]; Fabrikstrasse 23 - 29, D-73207 Plochingen (DE).

Veröffentlicht:

- Mit internationalem Recherchenbericht.
- Vor Ablauf der für Änderungen der Ansprüche geltenden Frist; Veröffentlichung wird wiederholt, falls Änderungen eintreffen.

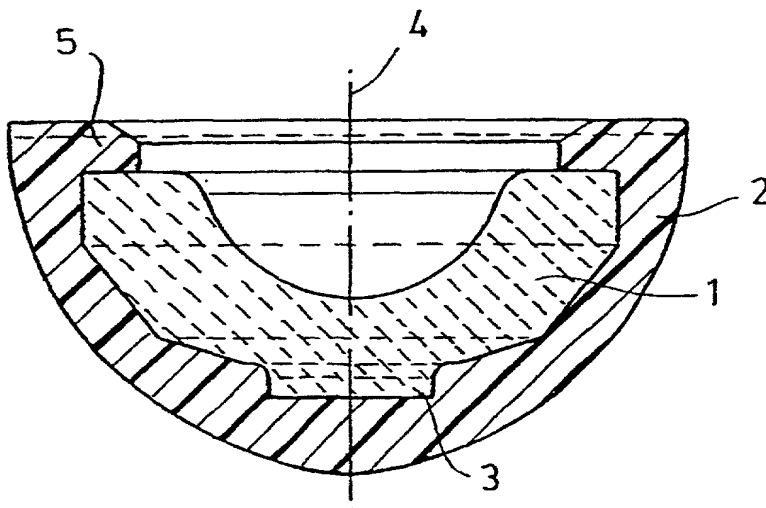
(72) Erfinder; und

(75) Erfinder/Anmelder (nur für US): **BUNZ, Uwe** [DE/DE]; Bergstrasse 10, D-72649 Wolfschlügen (DE). **HOCH, Ernst** [DE/DE]; Talstrasse 25, D-73274 Notzingen (DE).

Zur Erklärung der Zweibuchstaben-Codes, und der anderen Abkürzungen wird auf die Erklärungen ("Guidance Notes on Codes and Abbreviations") am Anfang jeder regulären Ausgabe der PCT-Gazette verwiesen.

(54) Title: CERAMIC SANDWICH INSERT FOR AN ARTIFICIAL HIP JOINT

(54) Bezeichnung: SANDWICH-INSERT AUS KERAMIK FÜR EIN KÜNSTLICHES HÜFTGELENK



(57) Abstract: The invention relates to a sandwich insert, comprising an inner ceramic sliding cup (1) that is surrounded by a plastic cover (2), for inserting into an outer, metal cup of an artificial hip joint. According to the invention, the sliding cup (1) has a stud (3) on the outer end facing towards the opening, in order to increase its resistance to impact while using minimal construction space.

(57) Zusammenfassung:

Die Erfindung betrifft ein Sandwich-Insert mit einer inneren Gleitschale (1) aus Keramik, die von einem Kunststoffmantel (2) umschlossen ist, zum Einsetzen in eine äußere Metallschale eines künstlichen Hüftgelenks. Zur

Erhöhung der Umschlagfestigkeit bei kleinem Bauraumbedarf wird vorgeschlagen, daß die Gleitschale (1) an ihrem der Öffnung abgewandten äußeren Ende einen Zapfen (3) aufweist.

WO 01/05338 A1

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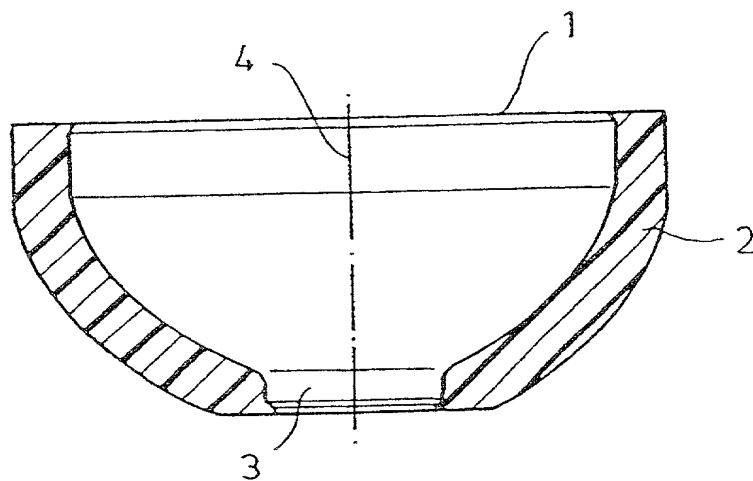


FIG. 1

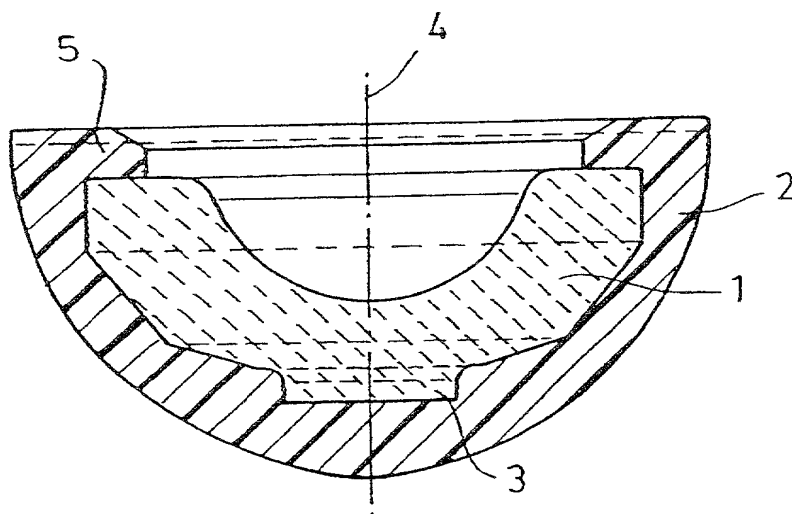


FIG. 2

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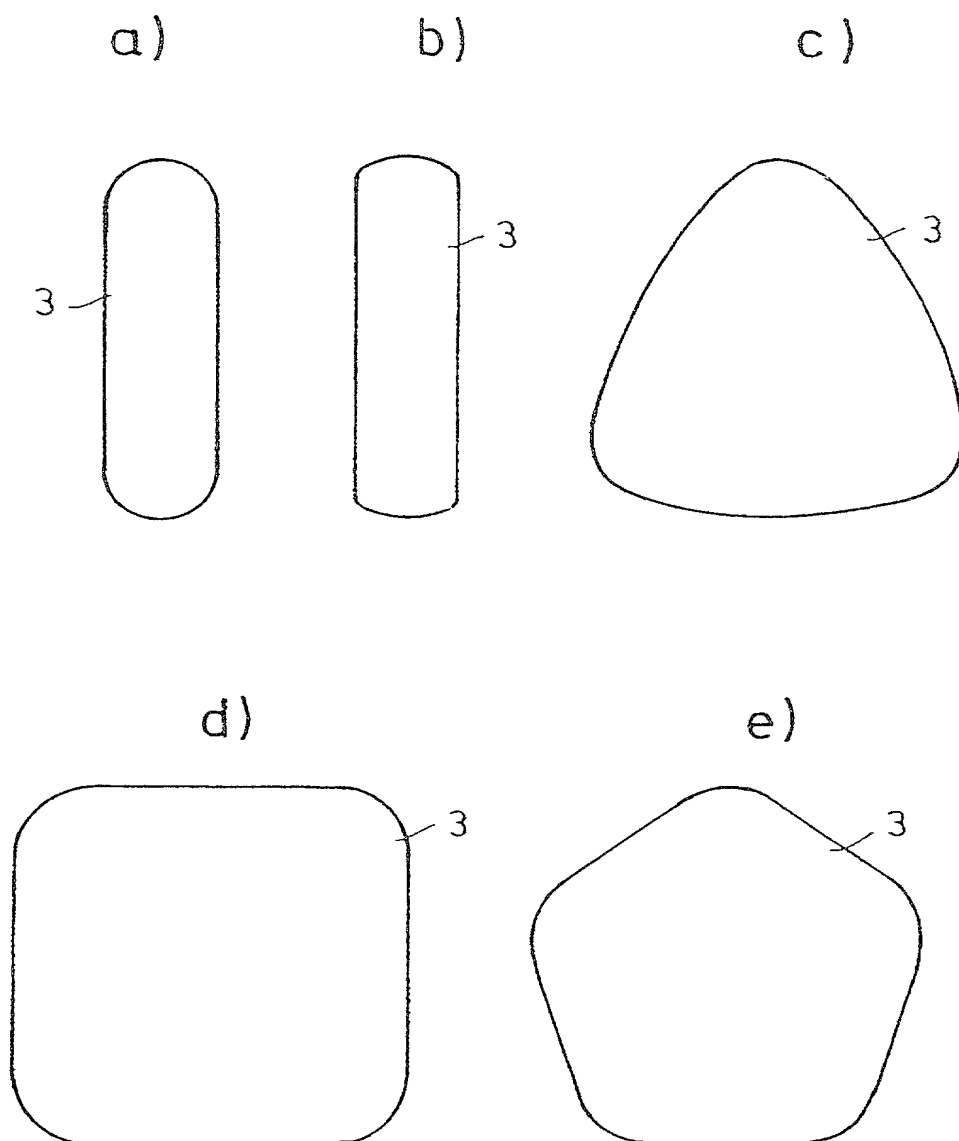


FIG. 3

#4

Docket No.

CERA 236

Declaration and Power of Attorney for Patent Application English Language Declaration

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

CERAMIC SANDWICH INSERT FOR AN ARTIFICIAL HIP JOINT

the specification of which (check one)

☐ Is attached hereto.

☒ was filed on January 4, 2002
as United States Application No. or PCT International Application No. 10/019,793
and was amended on _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, Section 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, Section 119(a)-(d) or Section 365(b) of any foreign application(s) for patent or inventor's certificate, or Section 365(a) of any PCT international application which designated at least one country other than the United States, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate or PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application(s)

			Priority Not Claimed
<u>199 33 206.1</u> (Number)	<u>DE</u> (Country)	<u>July 15, 1999</u> (Filing Date)	<input type="checkbox"/>
<u>100 00 521.7</u>	<u>DE</u>	<u>January 8, 2000</u>	<input type="checkbox"/>

PATENT Docket No.
Serial No.

Page 2 of 3

I hereby claim the benefit under 35 U.S.C. Section 119(e) of any United States provisional application(s) listed below:

_____ (Application Serial No.)	_____ (Filing Date)
_____ (Application Serial No.)	_____ (Filing Date)
_____ (Application Serial No.)	_____ (Filing Date)

I hereby claim the benefit under 35 U.S.C. Section 120 of any United States application(s), or Section 365(c) of any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. Section 112, I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, CFR, Section 1.56 which became available between the filing date of the prior application and the national or PCT International filing date of this application:

_____ (Application Serial No.)	_____ (Filing Date)	_____ (Status) (patented, pending, abandoned)
_____	_____	_____
_____ (Application Serial No.)	_____ (Filing Date)	_____ (Status) (patented, pending, abandoned)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

20020503 0646TDDT

PATENT Docket No.
Serial No.

Page 3 of 3

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith:

Peter F. Felfe, Reg. No. 20,297, Norman D. Hanson, Reg. No. 30,946, John A. Bauer, Reg. No. 32,554, James R. Crawford, Reg. No. 39,155, Andrew Im, Reg. No. 40,657 and David Rubin, Reg. No. 40,314, my attorneys with full power of substitution and revocation.

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PATENT Docket No.
Serial No.

Page 4 of 3

3-00

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Third inventor's signature <i>HGM</i>	Date 25.04.2002
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Full name of Fifth Inventor Robert RACK	
Fifth inventor's signature	Date
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Citizenship German	
Post Office Address SAME AS ABOVE	

PATENT Docket No.
Serial No.

Page 4 of 3

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Post Office Address SAME AS ABOVE	

Full name of Fifth Inventor Robert RACK	
Fifth Inventor's signature R. Rack	Date 18.04.02
Residence Wiesbrunnenstrasse 3, D-73207 Plochingen, Germany DEX	
Citizenship German	
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